REMARKS/ARGUMENTS

In response to the Restriction Requirement dated September 18, 2009, Applicant elected Group I, claims 1-4, drawn to an implantable scaffold prosthesis. As such, the remaining claims 5-12 are withdrawn from examination. Furthermore, Applicant has elected species C, reconstructed areola and nipple region for prosecution on the merits.

Claims 1-4 are currently under examination. Claim 1 has been cancelled. Claims 2-4 are amended.

Applicant has amended the claims to further refine and clarify that which Applicant regards as the invention. In particular, claim 2 now recites that the attachment or growth promoting reagents consist essentially of those identified in (b) of the claim. Claims 3 and 4 now depend from claim 2 instead of claim 1. No new matter has been added by these amendments.

Discussion of the Written Description Rejection

The Examiner rejected claims 1 and 2 under 35 U.S.C. §112, second paragraph, for failing to point out and particularly claim the subject matter that Applicant regards as the invention. In particular, the Examiner rejected claims 1 and 2 as reciting the limitation "of the recipients", where there was no antecedent basis for the limitation in the claims. Applicant has cancelled claim 1 and deleted the limitation in claim 2, so that the claim now recites that the scaffold is molded into the shape of a mammalian skin epithelial feature or region.

As discussed above, for purposes of examination, the mammalian skin epithelial feature is the areola and nipple region. Applicant submits that the rejection is now moot, in view of Applicant's claim amendments, and respectfully requests withdrawal of this rejection.

Discussion of the Novelty Rejection

The Examiner rejected claims 1-4 under 35 U.S.C. §102(b), as anticipated by USP 6,852,330 to Bowman et al. According to the Examiner, Bowman et al. allegedly teach an biocompatible polymer substrate which has a scaffold and attachment reagents incorporated in it, and is molded into a desired soft tissue shape, including breast tissue. Applicant respectfully traverses this rejection.

Bowman et al. teach an implant that includes one or more layers of a bioabsorbable polymeric foam having pores with an open pore structure (Abstract, col. 2, lines 20-22, col. 3, lines 32-34). Bowman et al. teach that the foams can be made in a number of ways, including lyophilization, supercritical solvent foaming, gas injection extrusion, gas injection molding or casting with an extractable material (col. 9, lines 17-25). In addition, the implant material has a reinforcement component, which is preferably a mesh fabric that is biocompatible (col. 2, lines 22-24, col. 3, lines 34-38). The pores of the foam have an average diameter of 100 to 1000 μm, and preferably 150 to 500 μm (col. 3, lines 54-56). Bowman et al. teach that the open cells of the foam in the scaffold have to be of sufficient size to permit cell ingrowth and to house the effector (i.e., growth factors or cells) (col. 3, lines 51-54). The foam component of the implant is integrated with the reinforcement component so that the web or walls of the foam components that form pores penetrate the mesh of the reinforcement component and interlock with the reinforcement component (col.4, lines 16-20).

In addition, Bowman et al. teach that the reinforcement component comprises textiles with woven, knitted, warped knitted, non-woven and braided structures. Moreover, these structures are made of fibers such as monofilaments, yarns threads, braids or bundles of fibers (col. 7, lines 24-41).

In contrast, Applicant's claimed invention as now amended, is directed to a scaffold comprising one or more biopolymers, synthetic polymers or a combination thereof, in the form of a thin sheet, microparticles, or as a semi-solid block, and in which is embedded, or has incorporated within the scaffold during its synthesis, an attachment mixture consisting essentially of one or more of the following: fibronectin,

laminin, RGDS, bFGF conjugated with polycarbophil, EGF conjugated with polycarbophil, and heparin sulfate. The scaffold is molded into the desired shape and the attachment mixture is then added. See Applicant's specification, for example, at paragraphs [0012], [0018]-[0019], [0026]-[0028], and the examples.

Nowhere in Applicant's specification, or claims, is it taught that the scaffold is comprised of a polymer foam having an open cell structure. Furthermore, Applicant's scaffold does not contain a reinforcing component comprising a textile mesh made of polymeric fibers as taught in Bowman et al. Applicant respectfully points out that Applicant's scaffold comprises polymers that are hydrogels in either sheet form, microparticle form, or in a block form, and do not have pores or cells as found in a foamed polymer composition. Applicant has amended claim 2 to more clearly recite this feature.

Moreover, while Bowman et al. teach that at least one effector can be used, they only provide a non-specific list of many known growth factors or cell components or proteins, and they do not teach the use of an attachment reagent consisting essentially of one or more of the following: fibronectin, laminin, RGDS, bFGF conjugated with polycarbophil, EGF conjugated with polycarbophil, and heparin sulfate.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). With regard to claims 2-4, as currently amended, Bowman et al. do not teach a scaffold comprising one or more biopolymers, synthetic polymers or a combination thereof, that is in the form of a thin sheet, in microparticle form, or as a semi-solid block, and in which is embedded, or has incorporated within the scaffold during its synthesis, an attachment mixture consisting essentially of one or more of the following: fibronectin, laminin, RGDS, bFGF conjugated with polycarbophil, EGF conjugated with polycarbophil, and heparin sulfate. Bowman et al. teach an implant that includes one or more layers of a bioabsorbable polymeric foam having pores with an open pore structure, and having a reinforcement component, which is preferably a mesh fabric that is biocompatible and that the foam component of the

implant is integrated with the reinforcement component so that the web or walls of the foam components that form pores penetrate the mesh of the reinforcement component and interlock. As such, Bowman et al. do not teach each and every element of Applicant's amended claims, and therefore claims 2-4 cannot be anticipated under 35 U.S.C. § 102(b). Applicant respectfully requests withdrawal of the rejection.

Conclusion

Applicant respectfully submits that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Date: January 12, 2010

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